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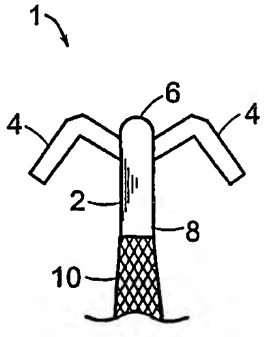
(54) Title: ANCHORING TO SOFT TISSUE



(57) Abstract: Soft tissue anchors can be used in various surgical procedures, including pelvic floor reconstruction procedures. The anchors have a first position that allows passage through the body and a second position that inhibits passage of the anchors back through the soft tissue when a pullback force is applied to the anchors by an implant, such as a surgical sling used for support of the urethra. The anchor may have a plurality of radially disposed support members (4) cantilevered laterally outward in the second position (Fig. 3) . In another embodiment the anchor has one or more support members, each of the support members (24) being wrapped around the central body element in the fist position (13) . In a third embodiment the tissue anchor may have a distal portion comprising one or more coils (14-15).

ANCHORING TO SOFT TISSUE

Technical Field

This invention generally relates to anchoring an implant within the body of a patient. More particularly, the invention relates to devices that anchor implants to soft tissue for use in surgical procedures, for example, pelvic floor reconstruction procedures.

Background Information

Certain urinary and gynecological pathologies can be treated by stabilizing an organ or tissue within the pelvic region. In female patients, examples of pathologies that can be treated by such a procedure include vaginal, uterine, and rectal prolapses, cystoceles, lateral defects, and urinary incontinence. A known method for stabilizing organs and tissues within the pelvic region involves the use of bone anchors. Deployment of a bone anchor requires drilling a hole in a bone, either by using a separate drilling instrument or by utilizing the anchor itself as a drilling tool. Bone anchors generally have one or more barbs that project outward to prevent the anchor from exiting the hole. Such anchors generally are not amenable to implantation in soft tissues, since the barbs would tear the soft tissue, causing irritation and/or passage of the anchor back through the tissue.

Other known methods include making one or more incisions in a patient's abdomen. For example, one method for treating female stress urinary incontinence involves supporting the urethra with an implant anchored in the patient's skin after the implant has been passed through the skin of the patient's abdomen.

Summary of the Invention

The present invention relates to devices that anchor implants to soft tissue for use in surgical procedures, for example, pelvic floor reconstruction procedures. The devices, or soft tissue anchors, and the delivery systems for the anchors generally are for use by surgeons and/or other medical professionals. Anchors according to the invention can be used to treat, for example, female stress urinary incontinence (SUI) by using an appropriate delivery system to deliver one or more anchors and a corresponding implant (such as a urethral sling) transvaginally, thus avoiding altogether the need for abdominal incisions. The structural tear resistance of the abdominal muscle is used to provide a stable and durable anchoring point in

such transvaginal procedures. This results in a simpler and faster procedure than other therapies that involve making abdominal incisions and/or drilling into the pubic bone to place anchors. Although soft tissue anchors according to the invention preferably are used in transvaginal procedures, the anchors also can be used in other procedures that do require abdominal incisions. Soft tissue anchors according to the invention have one or more support members or arms that rest upon the surface of the soft tissue and provide pull-through support without irritating tissue. The anchors can be used in a variety of surgical procedures and can support a variety of implants, including a surgical mesh or a surgical sling. In general, a soft tissue anchor according to the invention has one position that allows passage through the soft tissue of a patient and another position that inhibits passage of the anchor through the penetrated soft tissue when a pull-back force is applied to the anchor by an implant, such as a urethral sling, that is coupled to the anchor.

In general, in one aspect, the invention features a soft tissue anchor that comprises a central body element and a plurality of support members radially disposed about the central body element. The central body element comprises a proximal portion that can receive an implant. Each of the support members can move between a first position, which permits passage of the anchor through the soft tissue, and a second position, which inhibits passage of the soft tissue anchor back through the soft tissue when a pull-back force is applied to the anchor by the implant.

Embodiments of this aspect of the invention can include the following features. Each of the support members can be cantilevered, with the first position being laterally inward proximate to the central body element and the second position being laterally outward from the central body element. Each of the support members can be biased in the second position. The support members can also be collapsible and expandable structures, with the second position being the collapsed position. The distal portion of the central body element can taper to a point for penetrating soft tissue. A soft tissue anchor with a pointed distal end can include support members that prevent the point from contacting soft tissue when in the second position. Alternatively, the central body element can define an aperture and a passageway through its center. The proximal portion of the central body element can include an aperture, an eyelet, a groove, or a lumen for receiving an implant. Alternatively, at least some of the proximal portion can include threads for receiving a mating member, which can be coupled to an implant. The

implant itself can include a surgical mesh, a surgical sling, or one or more sutures. The soft tissue anchor can be fabricated from at least one bio-compatible material, such as a metal or a polymer.

In general, in another aspect, the invention features a central body element comprising a proximal portion for receiving an implant and one or more support members disposed about the central body element. Each of the support members can move between a first position, wherein the support member is wrapped around the central body element to permit passage of the soft tissue anchor through the soft tissue, and a second position, wherein each of the support members is projected outward from the central body element to inhibit passage of the soft tissue anchor back through the soft tissue when a force is applied to the anchor by the implant.

Embodiments of this aspect of the invention can include the following features. Each of the one or more supports can be biased in the second position. The proximal portion of the central body element can include an aperture, an eyelet, a groove, a lumen, or threads, and the implant can include a surgical mesh, a surgical sling, or suture(s). The soft tissue anchor can be fabricated from at least one bio-compatible material, such as a metal or a polymer.

In general, in yet another aspect, the invention features a soft tissue anchor comprising a distal portion comprising one or more coils that, when acted upon by a restraining force, adopt a shape that permits passage of the anchor through soft tissue. Upon removal of the restraining force, the one or more coils return to the coiled shape which inhibits passage of the soft tissue anchor back through the soft tissue when a force is applied to the anchor. The soft tissue anchor also comprises a proximal portion that extends from the distal portion and receives an implant.

Embodiments of this aspect of the invention can include the following features. The coiled distal portion can lie substantially in the same plane as the longitudinal axis of the proximal portion, or it can lie in a different plane than the longitudinal axis of the proximal portion. The proximal portion of the central body element can include an aperture, an eyelet, a groove, a lumen, or threads, and the implant can include a surgical mesh, a surgical sling, or suture(s). The soft tissue anchor can be fabricated from at least one bio-compatible material, such as a metal or a polymer.

The foregoing and other objects, aspects, features, and advantages of the invention will become more apparent from the following description and from the claims.

Brief Description of the Drawings

In the drawings, like reference characters generally refer to the same parts throughout the different views. Also, the drawings are not necessarily to scale, emphasis instead generally being placed upon illustrating the principles of the invention.

Figure 1 is a side view of an embodiment of a soft tissue anchor coupled to an implant, according to the present invention.

Figure 2 is a side view of another embodiment of a soft tissue anchor, in a first position.

Figure 3 is a side view of the soft tissue anchor of Figure 2, but in a second position.

Figure 4 is a side view of another embodiment of a soft tissue anchor, in a first position.

Figure 5 is a side view of the soft tissue anchor of Figure 4, but in a second position.

Figure 6 is also side view of a soft tissue anchor of Figure 4, but in an alternative second position.

Figure 7 is a side view of another embodiment of a soft tissue anchor, in a first position.

Figure 8 is a side view of another embodiment of a soft tissue anchor, in an expanded first position.

Figure 9 is a side view of the soft tissue anchor of Figure 8, but in a collapsed second position.

Figure 10 is a side view of another embodiment of a soft tissue anchor with a distal portion that tapers to a point, with the distances D_1 and D_2 indicated.

Figure 11a is a side view of another embodiment of a soft tissue anchor, with a central body element that defines an aperture with a passageway through its center.

Figure 11b is a top view of the soft tissue anchor of Figure 11a.

Figure 12a is a top view of another embodiment of a soft tissue anchor, with a support member that forms a coil around the central body element, in a second position.

Figure 12b is a side view of the soft tissue anchor of Figure 12a.

Figure 13 is a top view of the soft tissue anchor of Figure 12a, but in a first position.

Figure 14a is a side view of another embodiment of a soft tissue anchor in a second position, and this anchor comprises an element with a coiled distal end that lies substantially in the same plane as the longitudinal axis of the element's proximal end.

Figure 14b is a top view of the soft tissue anchor of Figure 14a.

Figure 15a is a side view of another embodiment of a soft tissue anchor in a second position, and this anchor comprises an element with a coiled distal end that does not lie in the same plane as the longitudinal axis of the element's proximal end.

Figure 15b is a top view of the soft tissue anchor of Figure 15a.

Figure 16 is a side view of the soft tissue anchor of Figure 14 or Figure 15a, in a first position.

Figure 17 is a side view of another embodiment of a soft tissue anchor, with a proximal portion that includes an aperture for receiving an implant.

Figure 18 is a side view of another embodiment of a soft tissue anchor, with a proximal portion that includes an eyelet for receiving an implant.

Figure 19 is a side view of another embodiment of a soft tissue anchor, with a proximal portion that defines a lumen for receiving an implant.

Figure 20 is a side view of another embodiment of a soft tissue anchor, with a proximal portion that defines a groove for receiving an implant.

Figure 21 is a side view of another embodiment of a soft tissue anchor, with a proximal portion that includes threads for receiving an implant.

Figure 22a is a side perspective view of an embodiment of a soft tissue anchor delivery device.

Figure 22b is a magnified view of the distal end of the delivery device of Figure 22a.

Figure 23a is a view of an embodiment of a cartridge for use with the delivery device of Figure 22a and/or Figure 25.

Figure 23b is a magnified view of the distal end of an embodiment of the cartridge of Figure 23a.

Figure 24 is a view of a soft tissue anchor according to the invention releasably engaged by a groove in the distal end of the cartridge of Figure 23b.

Figure 25 is a side perspective view of another embodiment of a soft tissue anchor delivery device.

Figure 26 is a side perspective view of the delivery device of Figure 25, with the cartridge of Figure 23a inserted and in position A.

Figure 27 is a view corresponding to Figure 26, with the cartridge in position B.

Figure 28 is a view corresponding to Figure 26, with the cartridge in position C.

Figure 29 is a view of another embodiment of a cartridge, with a distal portion that tapers to a point.

Figure 30 is a view of the pointed distal end of the cartridge of Figure 29, with the soft tissue anchor of Figures 11a and 11b disposed thereon.

Figure 31 is a side perspective view of the delivery device of Figure 25, with the cartridge of Figure 29 inserted and in position A.

Figure 32 is a view corresponding to Figure 31, with the cartridge in position B.

Figure 33 is a view corresponding to Figure 31, with the cartridge in position C.

Figure 34 is a cross section of a female patient's pelvic region.

Figure 35 is a cross section corresponding to Figure 34, showing a delivery device according to the invention just prior to passage through the rectus abdominus.

Figure 36 is a cross section corresponding to Figure 34, showing a delivery device according to the invention just after passage through the rectus abdominus.

Figure 37 is a cross section corresponding to Figure 34, showing a soft tissue anchor according to the invention in place between the rectus abdominus and the subcutaneous fat layer and an implant leading from the soft tissue anchor, through the endopelvic fascia, and out through the vagina.

Figure 38 is a sectional view of a female patient's pelvic region, showing an implant supported by two soft tissue anchors according to the invention.

Figure 39 is a sectional view corresponding to Figure 38, showing a soft tissue anchor according to the invention in place between the rectus abdominus and the subcutaneous fat layer and two sutures leading from the soft tissue anchor, through the endopelvic fascia, and out through the vagina.

Figure 40 is a sectional view corresponding to Figure 39, showing the two sutures after one has been moved to the opposite side of the urethra.

Figure 41 is a sectional view corresponding to Figure 39, showing the two sutures joined beneath the urethra and forming a loop around the urethra.

Description

In general, the invention relates to a soft tissue anchor for supporting an implant within the body of a patient. Referring to Figure 1, in one disclosed embodiment according to the invention, the soft tissue anchor 1 includes a central body element 2 from which a plurality of

support members 4 project. The central body element 2 includes a distal portion 6 and a proximal portion 8. The proximal portion 8 includes a structure, such as an aperture or an eyelet, to which an implant 10, such as a surgical mesh or sling, may be coupled. Ways of coupling the implant 10 to the proximal portion 8 include tying, threading, crimping, affixing with an adhesive, or the like. Other ways of coupling the implant 10 to the proximal portion 8 are also possible.

Referring to Figure 2 each support member 4 is a cantilevered support projecting from the central body element 2 at point 12. Each support member 4 is capable of pivoting at point 12 between a first position, illustrated by Figure 2, wherein the support member 4 is articulated inward toward the proximal portion 8 of central body element 2, and a second position, illustrated by Figure 3, wherein the support member 4 is articulated laterally away from the central body element 2. Each support member 4 can be biased in the second position such that it assumes that laterally extended second position when unrestrained. Alternatively, each support member 4 can be formed of a shape-memory material that assumes the second position upon, for example, a temperature change (from, for example, ambient/room temperature where it is in the first position to body temperature where it is in the second position).

Referring to Figure 4, in another embodiment, each support member 4 contains an elbow 14 that divides the support member 4 into an upper portion 16 and a lower portion 18. Each support member 4 is bent at the elbow 14 so that the lower portion 18 is deflected inward toward the central body element 2 in the proximal direction, defining an interior angle A_1 between the lower portion 18 and the upper portion 16 which is less than 180 degrees. Each support member 4 is capable of pivoting at point 12 between a first position, illustrated by Figure 4, wherein each support member 4 is articulated inward toward the proximal portion 8 of central body element 2, and a second position, illustrated by Figure 5, wherein each support member 4 is articulated laterally away from the central body element 2. Each support member 4 can be compliant and resilient and biased in the bent position at the elbow 14, whereby the interior angle A_1 is less than 180 degrees. When acted upon by a restraining force, the lower portion 18 of each support member 4 can be articulated such that the interior angle A_1 approaches or equals, but generally does not exceed, 180 degrees, as illustrated by Figure 6. When the restraining force is removed, each support member 4 can return to its bent position at the elbow 14.

Referring to Figure 7, in another embodiment, the soft tissue anchor 1 can adopt a first position wherein each support member 4 is pivoted at the point 12 inward toward the distal portion 6 of central body element 2. At the same time, the lower portion 18 of each support member 4 is bent in a proximal direction at the elbow 14, thereby reducing the interior angle A_1 between the upper portion 16 and the lower portion 18.

Referring to Figure 8, in another embodiment, each support member 4 is bent at a compliant elbow 14 that divides the support member 4 into an upper portion 16 and a lower portion 18. Each support member 4 is bent at the elbow 14 so that the lower portion 18 is deflected inward toward the central body element 2 in the proximal direction, defining an interior angle A_1 between the upper portion 16 and the lower portion 18 which is less than 180 degrees. The soft tissue anchor 1 can adopt an expanded first position wherein each support member 4 is pivoted inward at the point 12 toward the lateral portion 8 of central body element 2. At the same time, each support member 4 may also be bent at the elbow 14 such that angle A_1 approaches or equals, but generally does not exceed, 180 degrees. Referring to Figure 9, the soft tissue anchor 1 can adopt a collapsed second position wherein the upper portion 16 of each support member 4 is pivoted laterally away from the central body element 2 at the point 12. At the same time, the elbow 14 is bent such that the angle A_1 is reduced, pivoting the lower portion 18 at the elbow 14 to a position closer to the upper portion 16. Each support member 4 can be biased in the collapsed second position, as illustrated by Figure 9. Alternatively, each support member 4 can be formed of a shape-memory material that assumes the collapsed second position upon, for example, a temperature change (from, for example, ambient/room temperature where it is in the expanded first position to body temperature where it is in the collapsed second position).

Referring to Figure 10, in one embodiment, the distal portion 6 of the central body element 2 is tapered to a point 20. Each support member 4 can be bent at the elbow 14 so that the lower portion 18 is deflected inward toward the central body element 2 in the proximal direction. As illustrated by Figure 10, when each support member 4 is in the second position, wherein each support member 4 is articulated laterally away from the central body element 2, the distance D_1 from the distal end of the central body element 2 to each elbow 14 is greater than the distance D_2 from the distal end of the central body element 2 to the tip of point 20. When the soft tissue anchor 1 according to this embodiment is positioned within the patient, the patient's

anterior tissue will contact each elbow 14 rather than the point 20, thus protecting the anterior tissue from abrasion by the point 20.

Referring to Figures 11a and 11b, in another embodiment, the central body element 2 is hollow, defining an aperture 22 that runs through the length of central body element 2. The central body element 2 can be cylindrical, defining a round aperture 22. Alternatively, the central body element can be polygonal, defining a polygonal aperture.

Referring to Figures 12a and 12b, in another embodiment, the soft tissue anchor 1 contains a single support member 4 forming a coil 24 around a central body element 2. Referring to Figure 13, when acted upon by a restraining force, the soft tissue anchor 1 can adopt a first position wherein the coil 24 is wrapped tightly around the central body element 2, decreasing the diameter of the coil 24 to a smaller diameter d_s. Referring again to Figure 12a, when the restraining force is removed, the soft tissue anchor 1 can adopt a second position, wherein the coil 24 returns to its more loosely-coiled configuration with a larger diameter d_l.

Referring to Figures 14a and 14b, in another embodiment, the soft tissue anchor 1 comprises a compliant and resilient element 26 with a coiled distal portion 28 and an uncoiled proximal portion 30. The element 26 can be solid or can comprise a tube with its distal end closed. The coiled distal portion 28 can lie substantially in the same plane as the longitudinal axis of the uncoiled proximal portion 30, as illustrated in Figures 14a and 14b. Alternatively, the coiled distal portion 28 can lie in a different plane than the longitudinal axis of the uncoiled proximal portion 30, as illustrated by Figures 15a and 15b. Referring to Figure 16, when acted upon by a restraining force, the coiled distal portion 28 can be deformed into a configuration that is substantially linear with the longitudinal axis of the uncoiled proximal portion 30. This restraining force can be applied manually by the operator in preparation for loading the soft tissue anchor 1 into a delivery device, such as a cannula. When the soft tissue anchor 1 is in the delivery device, the delivery device itself provides the restraining force and maintains the soft tissue anchor 1 in the first position. When the soft tissue anchor 1 is ejected from the delivery device, the restraining force is removed and the distal portion 28 returns to its coiled configuration, illustrated alternatively by Figures 14a and 15a.

The proximal portion 8 can include any of a number of structures capable of coupling an implant to the soft tissue anchor 1. The structure can be an aperture 40, as illustrated by Figure 17, or an eyelet 42, as illustrated by Figure 18. The structure can also be a lumen 44, as

illustrated by Figure 19, or a groove 46, as illustrated by figure 20. Alternatively, referring to Figure 21, at least some of the proximal portion 8 can contain threads 48 to which a threaded mating element can be coupled, and the mating element can have the implant coupled thereto in any of a variety of ways, such as tying, crimping, or affixing with an adhesive, for example.

A soft tissue anchor 1 described herein can be fabricated from one or more polymers, including polyolefin, polycarbonate, nylon, and/or other bio-compatible thermoplastic or thermoset materials. Alternatively, a soft tissue anchor 1 can be fabricated from one or more metals, including stainless steel, titanium, tantilum, and/or other bio-compatible metals, or it can be fabricated from a metal alloy, such as nickel/titanium or Nitinol.

In one embodiment, the implant 10 is a surgical mesh. The surgical mesh can be fabricated from one or more bio-compatible materials, including polypropylene, polyesters, polyolefins, polytetrafluoroethylene, polyethylene, polyurethanes, nylons, and co-polymers thereof. Alternatively, the surgical mesh can be fabricated from naturally occurring tissue, or a hybrid of synthetic materials and naturally occurring tissues. The surgical mesh may also be made of absorbable materials, such as polyglycolic acid and polylactic acid.

Alternatively, the implant 10 can be a tape or a sling. The tape or sling may be fabricated from any of a variety of synthetic and/or naturally occurring bio-compatible materials. Such materials may be filamentous or non-filamentous, elastic or inelastic, and may be porous, microporous, perforated, or impermeable. The properties of the tape or sling may be selected based on the type of soft tissue anchor to which it will be coupled and the application for which the tape or sling will be used.

The implant 10 can also be one or more sutures. The suture(s) can be fabricated from one or more bio-compatible materials, including polypropylene, polyesters, polyolefins, polytetrafluoroethylene, polyethylene, polyurethanes, nylons, and co-polymers thereof.

The implant 10 may be coupled to the soft tissue anchor 1 by a number of methods, including tying, threading, crimping, affixing with an adhesive, or the like. The choice of the method of coupling to the proximal portion 8 is determined by the type of the implant 10 and the corresponding coupling structure of the soft tissue anchor 1. Alternatively, the soft tissue anchor 1 and the implant 10 can be fabricated as a single continuous unit.

The soft tissue anchor 1 is positioned within the patient's body by way of a delivery device, such as the delivery device 50 of Figure 22a. Referring to Figure 22a, in one

embodiment, the delivery device 50 includes a first cannula 52, a second cannula 54, a retractable trocar 56, a cartridge 58, and a handle 60. The retractable trocar 56 is operatively joined through the distal end of the handle 60 to a button 61.

Referring again to Figure 22a, the first cannula 52 and the second cannula 54 are cojoined lengthwise to form a probe 62, such that the lumen of the first cannula 52 and the lumen of the second cannula 54 are parallel. Referring to Figure 22b, the distal end of the first cannula 52 can extend beyond the distal end of the second cannula 54 in the probe 62. The first cannula 52 and the second cannula 54 are rigid and can be made of materials such as stainless steel, plated carbon steel, or coated carbon steel. The proximal end of probe 62 is joined to the distal end of the handle 60 at an aperture 64 so that the first cannula 52 is on the same side of the handle 60 as the button 61.

The probe 62 forms an arc from the distal end of the probe 62 to about 10-75% of the length of the probe 62. For example, referring to Figure 22a, the probe 62 forms an arc with the concave surface of the arc on the same side of the probe 62 as the button 61 of the handle 60. The arc of the probe 62 is selected to optimize the ease of insertion of the delivery system though the patient's tissues to position the implant 10 at the appropriate site within the patient's body.

The retractable trocar 56 is slidably positioned in the lumen of the first cannula 52. The point of the trocar 56 can be articulated from a retracted position to an extended position. The button 61 is operatively joined to the trocar 56. When the button 61 is depressed, the point of the trocar 56 is extended from the distal end of the first cannula 52. When the button 61 is released, the point of the trocar 56 is retracted into the first cannula 52. The button 61 is spring biased so that the operator must manually hold the button 61 down to extend the point of the trocar 56 from the distal end of the first cannula 52.

Referring to Figure 23a, the cartridge 58 is joined at its proximal end to a cartridge tab 66. Referring to Figure 23b, the distal end of the cartridge 58 can include a structure (for example, a groove 65) for releasably engaging the soft tissue anchor 1. The cartridge 58 is made of a flexible material so it can follow the arc of the second cannula 54. The cartridge 58 can be completely removed from the handle 60 to load the soft tissue anchor 1 and the implant 10 into the second cannula 54. The cartridge 58 is then slidably positioned within the lumen of the second cannula 54. The soft tissue anchor 1 is moved toward the distal end of the second cannula 54 by moving the cartridge tab 66 forward toward the distal end of the handle 60.

The first step in inserting the soft tissue anchor 1 into a patient's body is to load the soft tissue anchor 1 into the second cannula 54. The soft tissue anchor 1 can be inserted into the proximal end of the second cannula 54, followed by the cartridge 58. Alternatively, the soft tissue anchor 1 can first be engaged by a structure, such as a groove 65, included in the distal end of cartridge 58, as illustrated by Figure 24. The cartridge 58 is then inserted into the second cannula 54. While inside the second cannula 54, each of the support members 4 of the soft tissue anchor 1 assumes the first position. The cartridge tab 66 is pushed toward the distal end of the handle 60 so that the soft tissue anchor 1 does not extend beyond the distal end of the second cannula 54.

The distal end of probe 62 is then inserted into a body cavity. As the probe 62 is advanced within the body cavity, the button 61 is depressed to extend the trocar 56 from the distal end of the first cannula 52 when it is necessary to penetrate and pass through soft tissue. Likewise, the button 61 is released to retract the trocar 56 into the first cannula 52 when no penetration is necessary. When the distal end of the probe 62 reaches the appropriate site within the body cavity, the cartridge tab 66 is moved as far distally as possible, which pushes the soft tissue anchor 1 out of the distal end of the second cannula 54. Once the soft tissue anchor 1 has left the distal end of the second cannula 54, each of the support members 4 assumes the second position, which inhibits the soft tissue anchor 1 from passing back through the soft tissue when a pull-back force is applied to the soft tissue anchor 1 by the implant 10. As soon as the soft tissue anchor 1 is in place, the probe 62 is removed from the body cavity, leaving the soft tissue anchor 1 and the implant 10 in place within the patient's body.

Referring to Figure 25, in another embodiment, the delivery device 50 is suitable for delivering a soft tissue anchor 1 that has a distal portion 6 that tapers to a point 20, as illustrated, for example, by Figure 10. The delivery device 50 includes a cannula 67, a cartridge 58, and a handle 60. The cannula 67 is rigid and can be made of a material such as stainless steel, plated carbon steel, or coated carbon steel. The proximal end of the cannula 67 is joined to the distal end of handle 60 at aperture 64.

The cannula 67 forms an arc from the distal end of the cannula 67 to about 10-75% of the length of the cannula 67 . For example, referring to Figure 25, the cannula 67 forms an arc with the concave surface of the arc on the same side of the cannula 67 as the top of the handle 60. The

arc of the cannula 67 is selected to optimize the ease of insertion of the delivery system though the patient's tissues to position the implant 10 at the appropriate site within the patient's body.

Referring again to Figure 23a, the cartridge 58 is joined at its proximal end to a cartridge tab 66. The distal end of the cartridge 58 can include a structure for releasably engaging the soft tissue anchor 1, for instance, a groove 65, as illustrated by Figure 23b. The soft tissue anchor 1 can be inserted into the proximal end of the cannula 67 followed by the cartridge 58. Alternatively, the soft tissue anchor 1 can be first engaged by the distal end of the cartridge 58, as illustrated by Figure 24, and then the cartridge 58 can be slid into the cannula 67. While inside the lumen of the cannula 67, each of the support members 4 of the soft tissue anchor 1 assumes the first position.

The cartridge 58 can move between three positions – positions A, B and C – by moving the cartridge tab 66 forward toward the distal end of the handle 50 and back toward the proximal end of the handle 50. Referring to Figure 26, in position A, no portion of the soft tissue anchor 1 extends beyond the distal end of the cannula 67. Referring to Figure 27, in position B, only the point 20 of the soft tissue anchor 1 is extended beyond the distal end of the cannula 67. Referring to Figure 28, in position C, the soft tissue anchor 1 is pushed out of the distal end of the cannula 67.

The soft tissue anchor 1 is inserted into a patient's body by first loading the soft tissue anchor 1 into the cannula 67. As the cannula 67 is inserted into the body cavity, the cartridge tab 66 is moved to position B, where the point 20 extends from the distal end of the cannula 67, when it is necessary to penetrate and pass through soft tissue. The cartridge tab 66 is moved to position A, where the point 20 is retracted within the distal end of the cannula 67, when no penetration is necessary. When the distal end of the cannula 67 reaches the appropriate anatomical site, the cartridge tab 66 is moved to position C, which pushes the soft tissue anchor 1 out of the distal end of the cannula 67. Once the soft tissue anchor 1 has left the distal end of the cannula 67, each of the support members 4 assumes the second position, which inhibits the soft tissue anchor 1 from passing back through the soft tissue when a pull-back force is applied to the soft tissue anchor 1 by the implant 10. As soon as the soft tissue anchor 1 is in place, the cannula 67 is removed from the body cavity, leaving the soft tissue anchor 1 and the implant 10 in place within the patient's body.

In another embodiment, the delivery device 50 illustrated by Figure 25 is used to deliver a soft tissue anchor 1 that has a hollow central body element 2, as illustrated, for example, by Figures 11a and 11b. In this embodiment, the distal end of the cartridge 58 tapers from an edge 68 to a point 70, as illustrated by Figure 29. Referring to Figure 30, when the cartridge 58 is threaded through the aperture 22 in the soft tissue anchor 1, the point 70 extends beyond the distal end 6 of the soft tissue anchor 1, and the soft tissue anchor 1 can move no farther down the length of the cartridge 58 than the edge 68.

Referring again to Figure 25, the cartridge 58 is slid into the lumen of the cannula 67 of the delivery device 50. While inside the lumen of the cannula 67, each of the support members 4 of the soft tissue anchor 1 assumes the first position. The cartridge 58 can move between three positions – positions A, B and C – by moving the cartridge tab 66 forward toward the distal end of the handle 50 and back toward the proximal end of the handle 50. Referring to Figure 31, in position A, the point 70 of the cartridge 58 is fully retracted within the distal end of the cannula 67. Referring to Figure 32, in position B, only the point 70 of the cartridge 58 is extended beyond the distal end of the cannula 67. Referring to Figure 33, in position C, the soft tissue anchor 1 is pushed out of the distal end of the cannula 67.

The soft tissue anchor 1 is inserted into a patient's body by first threading the distal end of the cartridge 58 through the aperture in the soft tissue anchor 1. Cartridge 58 is inserted into the cannula 67. As the cannula 67 is inserted into the body cavity, the cartridge tab 66 is moved to position B, where the point 70 extends from the distal end of the cannula 67, when it is necessary to penetrate and pass through soft tissue. The cartridge tab 66 is moved to position A, where the point 70 is retracted within the distal end of the cannula 67, when no penetration is necessary. When the distal end of the cannula 67 reaches the appropriate site within the body cavity, the cartridge tab 66 is moved to position C, which pushes the soft tissue anchor 1 out of the distal end of the cannula 67. Once the soft tissue anchor 1 has left the distal end of the cannula 67, each of the support members 4 assumes the second position, which inhibits the soft tissue anchor 1 from passing back through the soft tissue when a pull-back force is applied to the soft tissue anchor 1 by the implant 10. As soon as the soft tissue anchor 1 is in place, the cannula 67 is removed from the body cavity, leaving the soft tissue anchor 1 and the implant 10 in place within the patient's body.

The foregoing descriptions of delivery devices and systems for positioning a soft tissue anchor within a patient's body illustrative and not restrictive. A suitable delivery device or system can be embodied in other specific forms.

The present invention can find use in a number of female pelvic floor reconstruction procedures, including the correction of vaginal, uterine, and rectal prolapses, repair of cystoceles, lateral defect repair, and for the treatment of urinary incontinence. The present invention also can be useful in procedures dealing with male patients. In one embodiment, the soft tissue anchor 1 is used to support a surgical mesh used for the treatment of female stress urinary incontinence (SUI).

Figure 34 illustrates a simplified cross-sectional view of a female patient's pelvic region. The bladder 100 is located behind the pubic bone 102. The urethra 104 extends from the bladder 100 toward the urinary meatus 105. The upper portion of the urethra 104 constitutes the urethrovesical junction 106, or the bladder neck. Support of the middle portion 107 of the urethra 104, between the urethrovesical junction 106 and the urinary meatus 105, is believed to be important for the treatment of SUI. The uterus 108, located behind the bladder 100, leads to the vagina 110. The rectum 112 is located behind the vagina. The rectus abdominus muscle 116, which is attached to the pubic bone 102 by Cooper's ligament 114, is located above the bladder 100 and the uterus 104. A subcutaneous fat layer 118 is located between the rectus abdominus 116 and the skin 120.

The maintenance of normal female continence depends upon the proper support and stabilization of the bladder 100 and the urethra 104, especially during period of abdominal stress, such as when the patient coughs or laughs. SUI can be caused by the weakening or stretching of the ligaments or other tissues that support the urethra 104 to the point where the urethra 104 cannot prevent the release of urine during periods of abdominal stress. The present invention can be used to treat SUI by providing the urethral support necessary to maintain urinary continence.

Referring to Figure 35, a soft tissue anchor 1, to which a surgical mesh 122 has been coupled, is loaded into a delivery device 50, which includes a first cannula 52 and a second cannula 54 that are cojoined lengthwise to form a probe 62. An incision 124 is made in the vaginal wall 125 directly beneath the urethra 104. The distal end of the probe 62 is inserted into the incision 124, and the probe is guided along one side of the urethra 104. The retractable trocar

56 is extended from the distal end of the first cannula 52 in order to pierce the endopelvic tissue 126 and move the probe upward toward the rectus abdominus 116.

Referring to Figure 36, once the distal end of the probe 62 pierces the rectus abdominus 116, the trocar 56 is retracted into the first cannula 52, and the probe 62 is advanced further, pushing the subcutaneous fat layer 118 upward and separating it from the rectus abdominus 116, but not penetrating it. The soft tissue anchor 1 is ejected from the distal end of the second cannula 54 by advancing the cartridge tab 66 toward the distal end of the handle 60. Once the soft tissue anchor 1 is deployed, the probe 62 is pulled back out of the incision, leaving the soft tissue anchor 1 resting on the rectus abdominus 116 beneath the subcutaneous fat layer 118.

As the probe 62 is removed, the surgical mesh 122, which is coupled to the embedded soft tissue anchor 1, is pulled out of the distal end of the second cannula 54. Referring to Figure 37, the surgical mesh 122 trails from the soft tissue anchor 1, through the endopelvic tissue 126 along one side of the urethra 104, and into the vagina 110 through the incision 124 in the vaginal wall 125. The end of the surgical mesh 122 which is trailing in the vagina typically is already coupled to a second soft tissue anchor 1', which is then loaded into the delivery device 50. The above procedure is repeated, advancing the probe 62 along the other side of the urethra 104 and implanting the second soft tissue anchor 1' between subcutaneous fat layer 118 and the rectus abdominus 116. Referring to Figure 38, the surgical mesh 122, held in position by the two tissue anchors 1 and 1', provides the urethral support necessary for the treatment of SUI.

Although the above description refers to a surgical mesh, a number of different implant structures and materials could be employed with the current invention, including one or more sutures or a surgical sling, for example.

Alternatively, a single soft tissue anchor 1 can be used to anchor an implant to soft tissue for use in pelvic floor reconstruction procedures, such as the treatment of SUI. For example, referring to Figure 39, a soft tissue anchor 1 that is coupled to two sutures, 130 and 132, can be implanted between subcutaneous fat layer 118 and the rectus abdominus 116 as described above. One of the sutures can then be passed back through the incision 124 in the vaginal wall 125, over the urethra 104, and through a second incision 136 in the vaginal wall 125, as illustrated by Figure 40. The ends of the two sutures 130 and 132 can then be joined together beneath the urethra 104, forming a loop around the urethra 104, as illustrated by Figure 41. The ends of the

two sutures can also be joined to another implant, such as a surgical mesh or surgical sling, placed beneath the urethra.

The implant used for pelvic floor reconstruction procedures can be pre-coupled to one or more soft tissue anchors according to the invention, and this implant/anchor unit can be sold separately or together with a suitable delivery system. Surgeons and/or other medical professionals can then use the implant/anchor unit to perform surgical procedures, for example, pelvic floor reconstruction procedures.

The invention may be embodied in other specific forms without departing from the spirit or essential characteristics thereof. The disclosed embodiments are to be considered in all respects illustrative and not restrictive. The scope of the invention is not limited just to the disclosed embodiments.

What is claimed is:

Claims

1. A soft tissue anchor, comprising:
   a. a central body element comprising a proximal portion for receiving an implant; and
   b. a plurality of support members radially disposed about the central body element, each of the support members movable between a first position that permits passage of the anchor through the soft tissue and a second position that inhibits passage of the soft tissue anchor back through the soft tissue when a force is applied to the anchor by the implant.

2. The soft tissue anchor of claim 1 wherein each of the plurality of support members is cantilevered with the first position being laterally inward proximate to the central body element and the second position being laterally outward from the central body element.

3. The soft tissue anchor of claim 2 wherein each of the plurality of support members is biased in the second position.

4. The soft tissue anchor of claim 1 wherein the plurality of support members are collapsible and expandable structures with the second position being the collapsed position.

5. The soft tissue anchor of claim 1 wherein the central body element further comprises a distal portion that tapers to a point for penetrating soft tissue.

6. The soft tissue anchor of claim 5 wherein the distal portion of the central body element is prevented from contacting soft tissue when each of the plurality of support members is in the second position.

7. The soft tissue anchor of claim 1 wherein the central body element defines an aperture and a passageway through its center.

8. A soft tissue anchor, comprising:
   a. a central body element comprising a proximal portion for receiving an implant; and
   b. one or more support members disposed about the central body element, each of the support members movable between a first position wherein the support member is wrapped around the central body element to permit passage of the soft

tissue anchor through the soft tissue, and a second position wherein the support member is projected outward from the central body element to inhibit passage of the soft tissue anchor back through the soft tissue when a force is applied to the anchor by the implant.

9. The tissue anchor of claim 8 wherein each of the one or more supports is biased in the second position.

10. A soft tissue anchor, comprising:

a. a distal portion comprising one or more coils that, when acted upon by a restraining force, can adopt a shape that permits passage of the anchor through soft tissue, and, upon removal of the restraining force, can return to the coiled shape which inhibits passage of the soft tissue anchor back through the soft tissue when a force is applied to the anchor by the implant; and

b. a proximal portion extending from the distal portion and for receiving an implant.

11. The soft tissue anchor of claim 10 wherein a plane defined by the coiled distal portion is substantially parallel to the longitudinal axis of the proximal portion.

12. The soft tissue anchor of claim 10 wherein a plane defined by the coiled distal portion is substantially perpendicular to the longitudinal axis of the proximal portion.

13. The soft tissue anchor of claim 1 wherein the proximal portion includes a structure for receiving the implant, the structure selected from the group consisting of an aperature, an eyelet, a lumen, and a groove.

14. The soft tissue anchor of claim 1 wherein at least some of the proximal portion includes threads.

15. The soft tissue anchor of claim 1 wherein the implant is selected from the group consisting of a surgical mesh, a surgical sling, and at least one suture.

16. The soft tissue anchor of claim 1 wherein the soft tissue anchor is made of at least one bio-compatible material.

17. The soft tissue anchor of claim 16 wherein the at least one bio-compatible material is selected from the group consisting of a metal and a polymer.

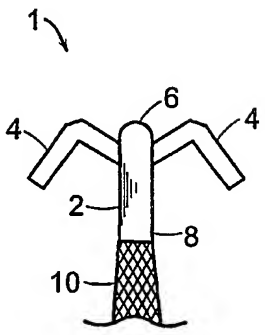


FIG. 1

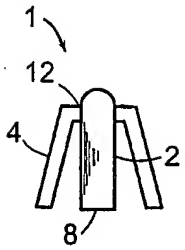


FIG. 2

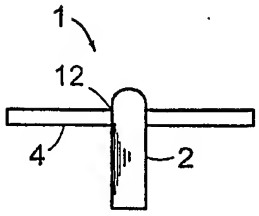


FIG. 3

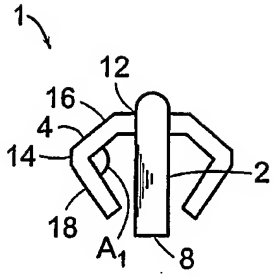


FIG. 4

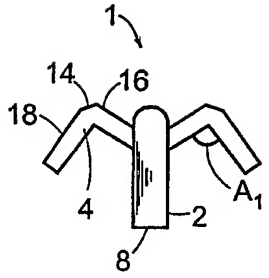


FIG. 5

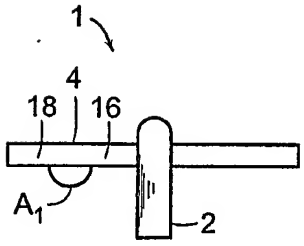


FIG. 6

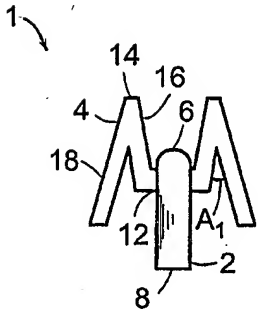


FIG. 7

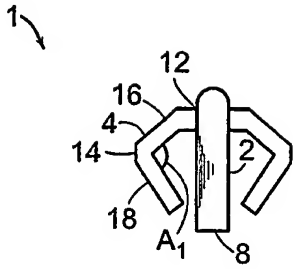


FIG. 8

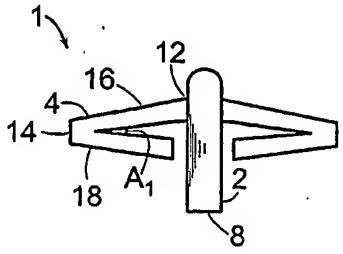


FIG. 9

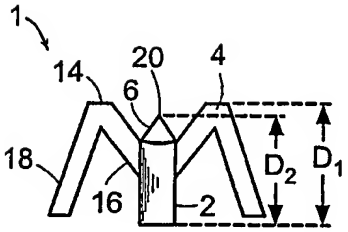


FIG. 10

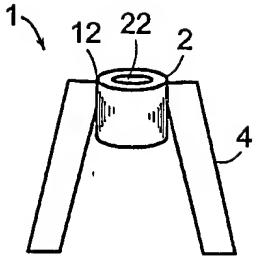


FIG. 11A

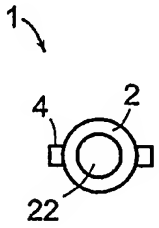


FIG. 11B

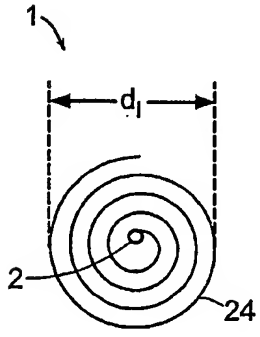


FIG. 12A

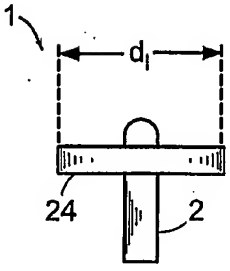


FIG. 12B

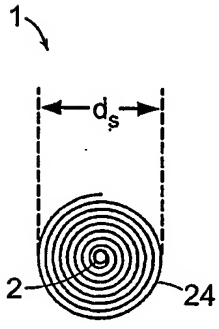


FIG. 13

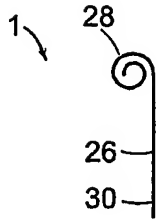


FIG. 14A

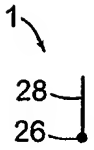


FIG. 14B

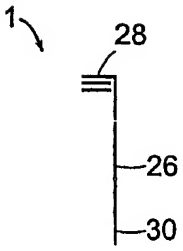


FIG. 15A

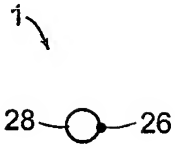


FIG. 15B

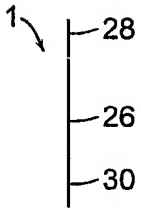


FIG. 16

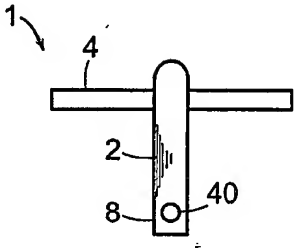


FIG. 17

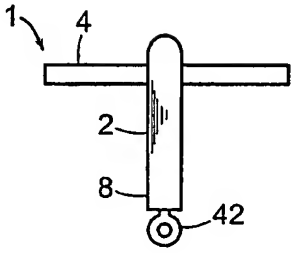


FIG. 18

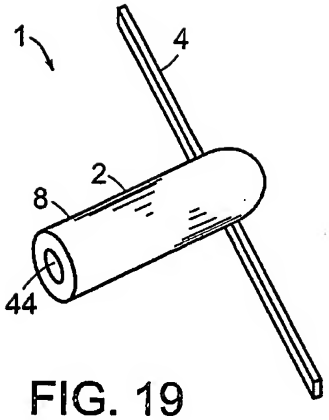


FIG. 19

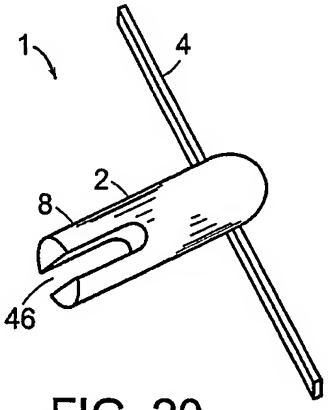


FIG. 20

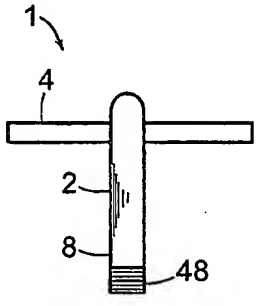


FIG. 21

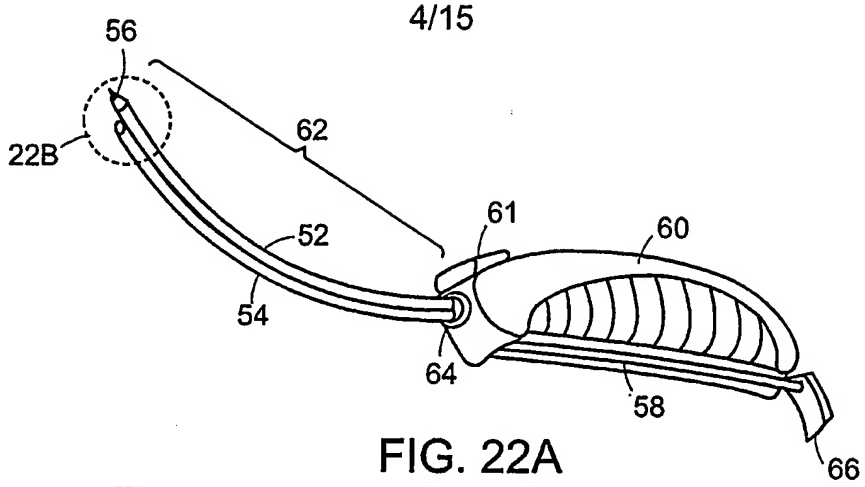


FIG. 22A

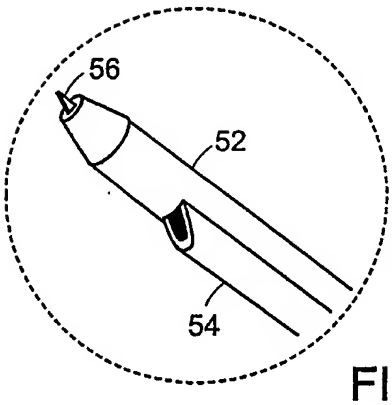


FIG. 22B

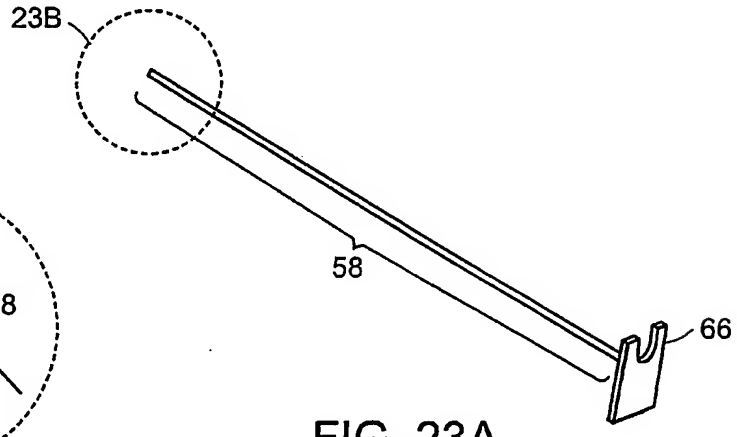


FIG. 23A

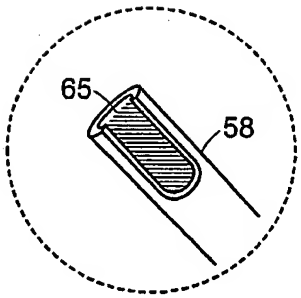


FIG. 23B

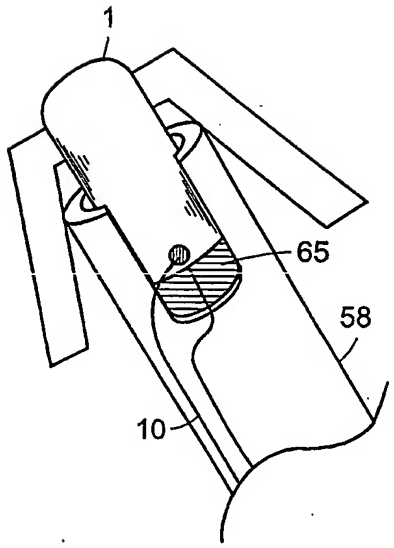


FIG. 24

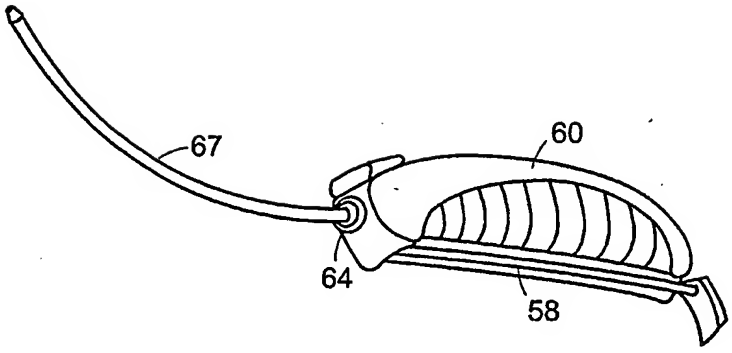


FIG. 25

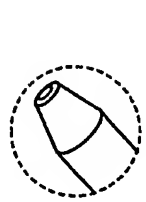


FIG. 26B

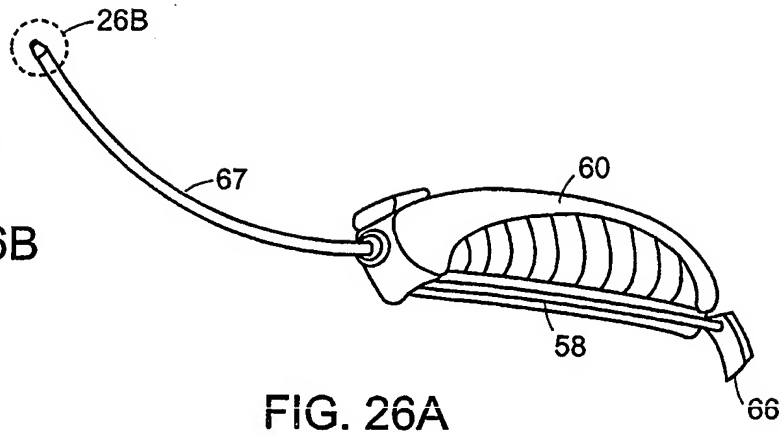


FIG. 26A

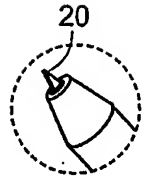


FIG. 27B

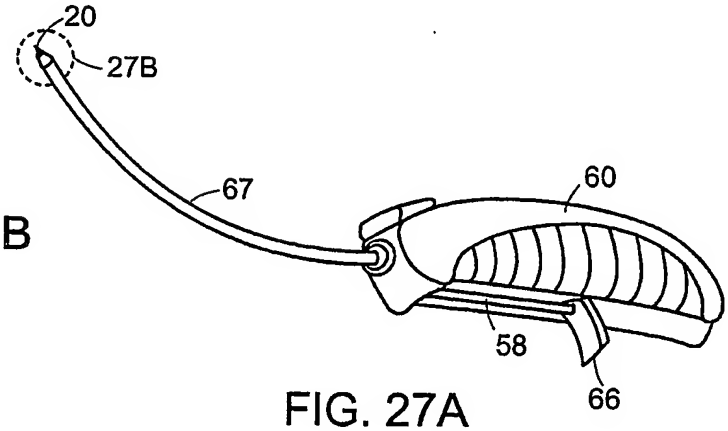


FIG. 27A

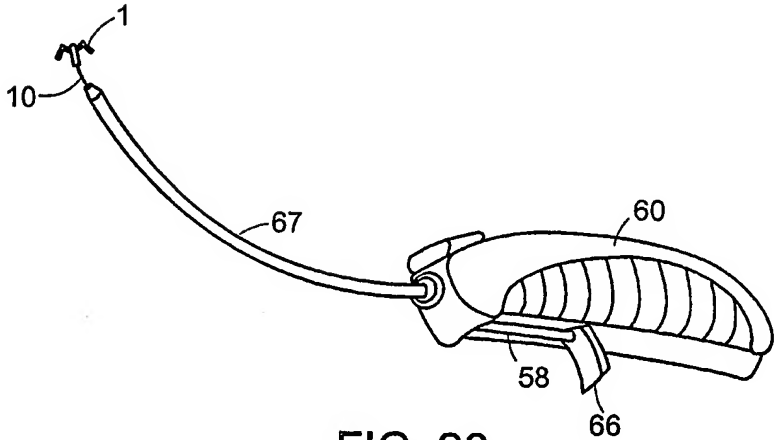


FIG. 28

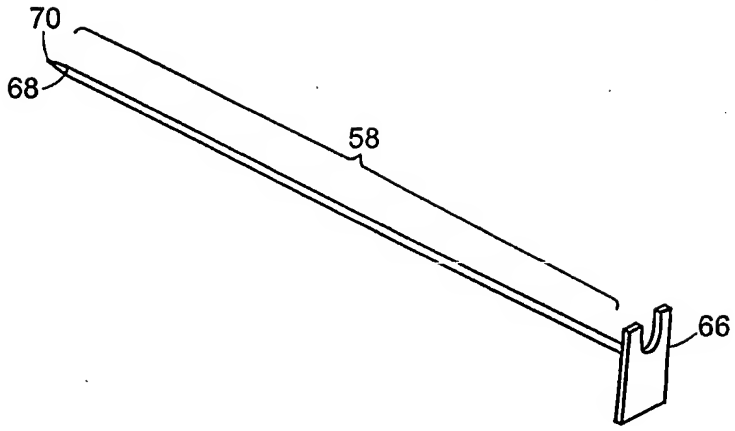


FIG. 29

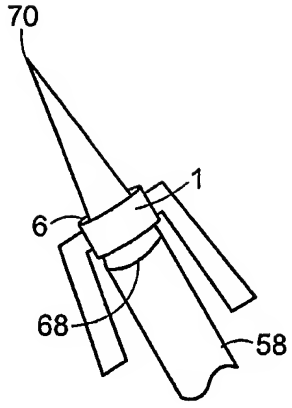


FIG. 30

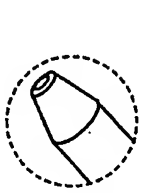


FIG. 31B

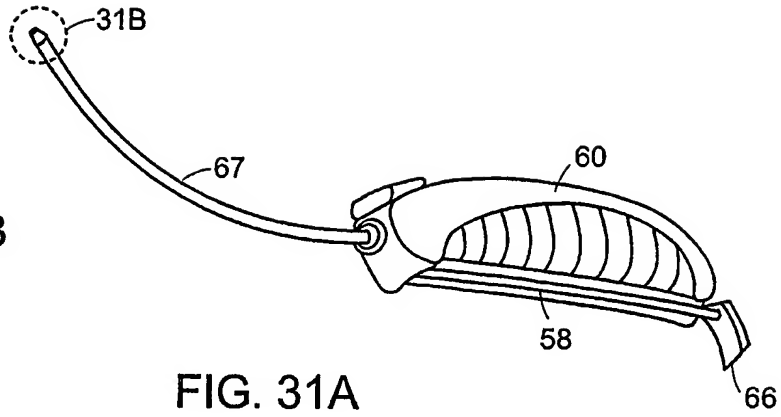


FIG. 31A

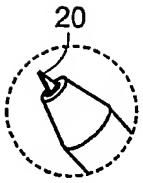


FIG. 32B

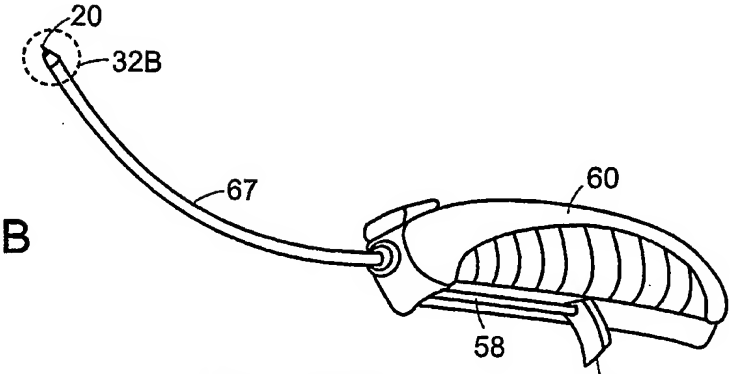


FIG. 32A

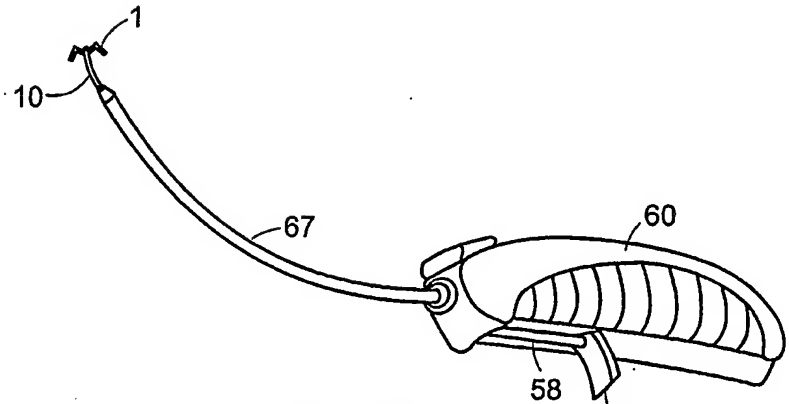


FIG. 33

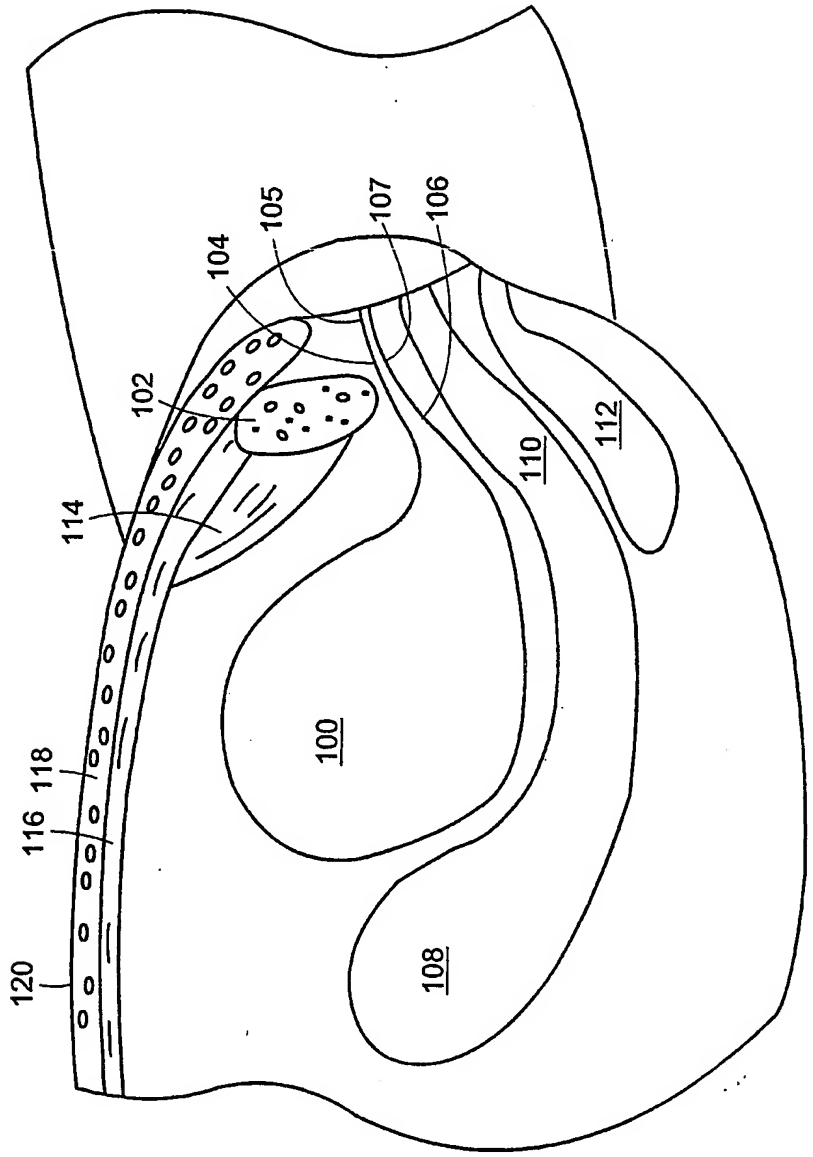


FIG. 34

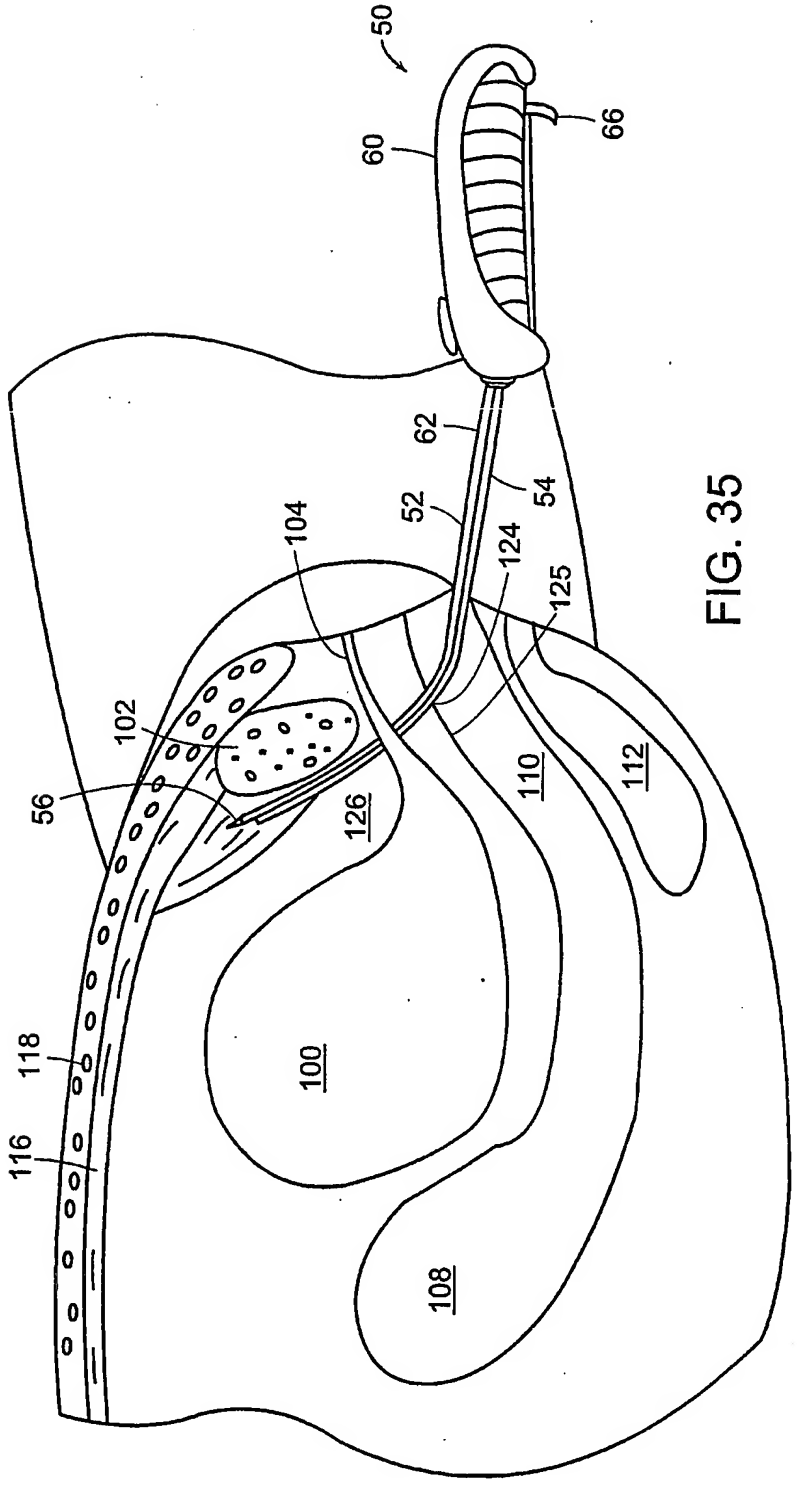


FIG. 35

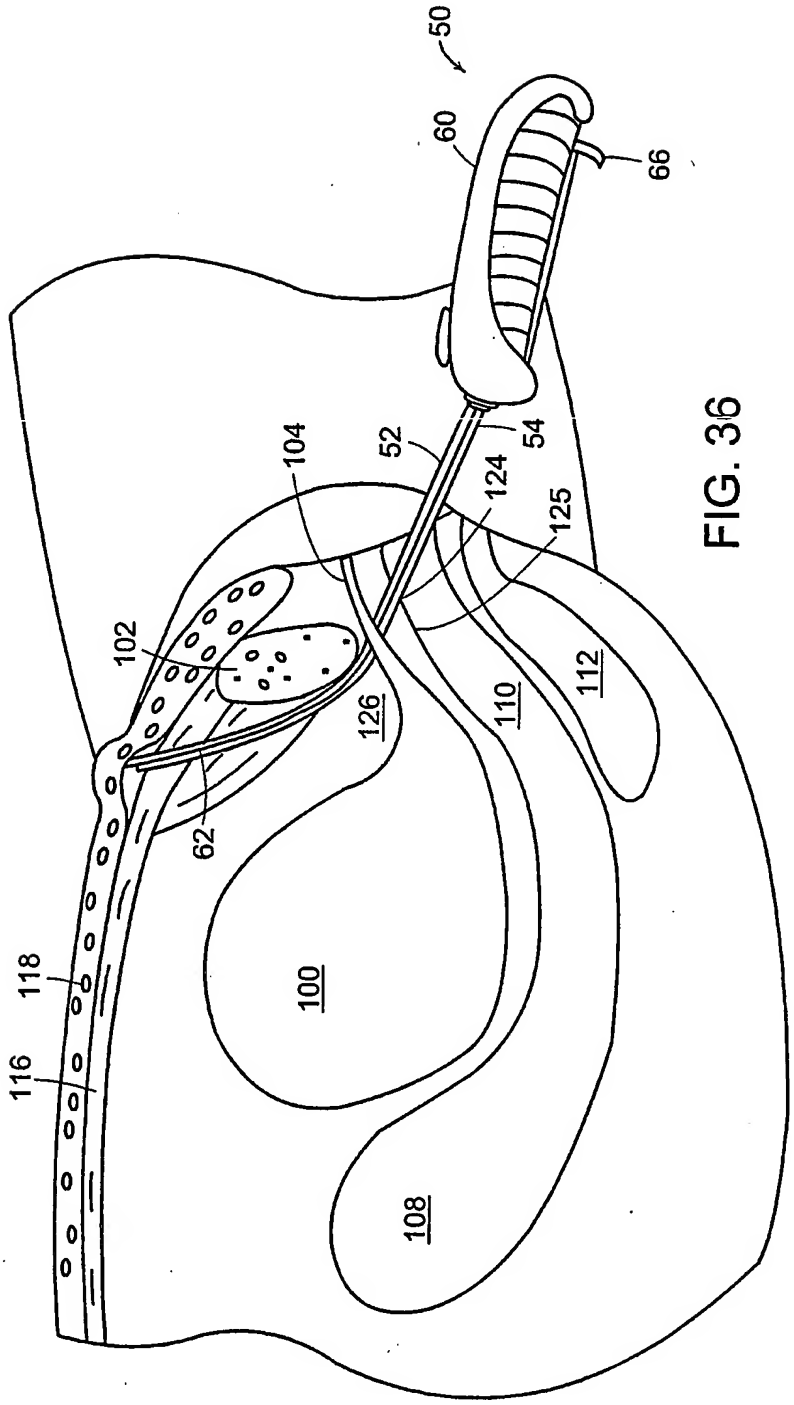


FIG. 36

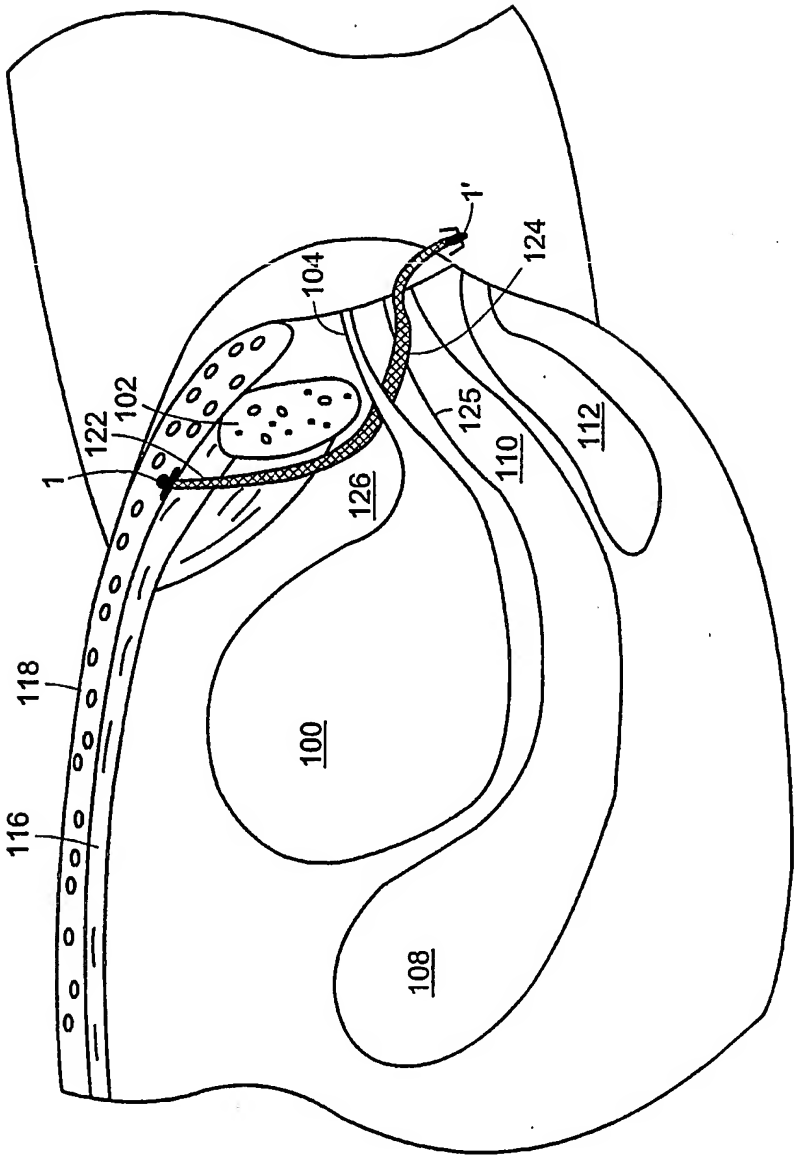


FIG. 37

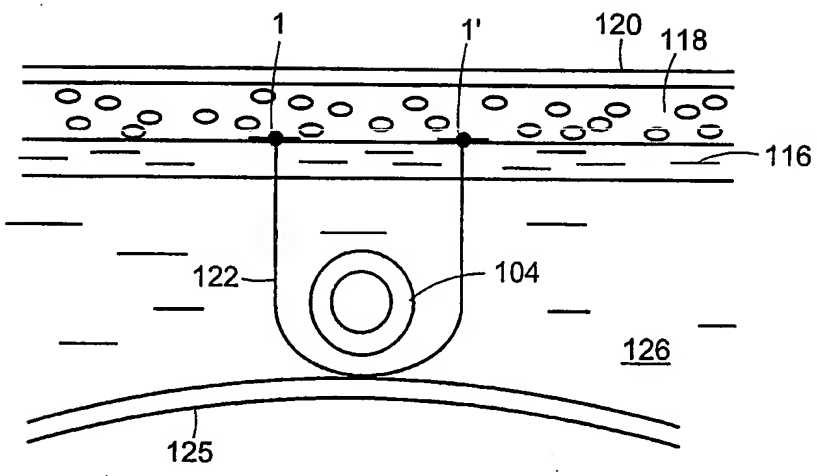
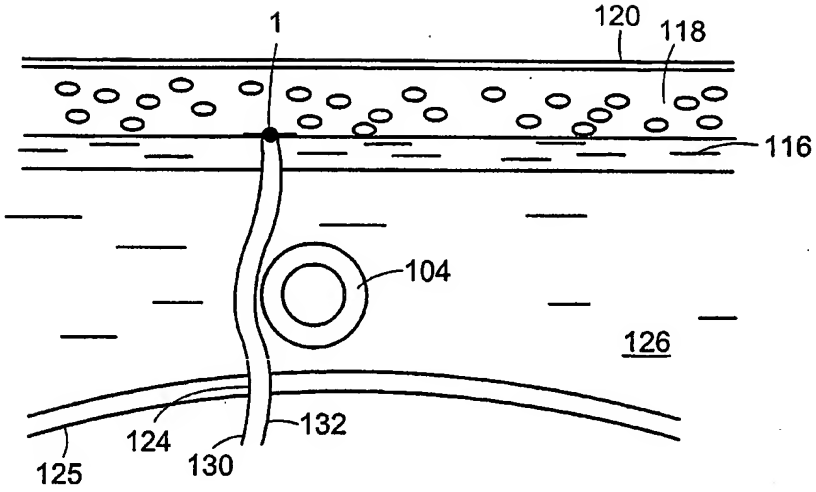


FIG. 38


1
120
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132
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130

FIG. 39

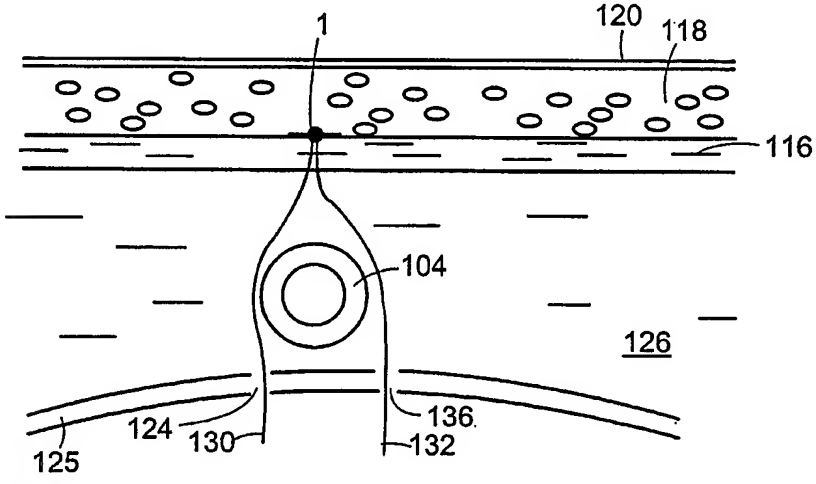
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FIG. 40

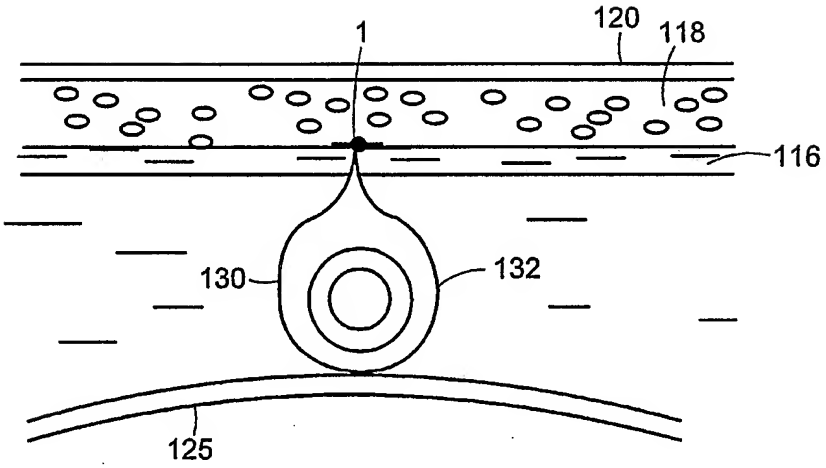

FIG. 41

INTERNATIONAL SEARCH REPORT

International Application No
PCT/US 03/40453

A. CLASSIFICATION OF SUBJECT MATTER
IPC 7 A61B17/04

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)
IPC 7 A61B A61F

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practical, search terms used)
EPO-Internal, WPI Data, PAJ

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category °	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	US 2002/161382 A1 (ANDERSON KIMBERLY A ET AL) 31 October 2002 (2002-10-31) paragraph '0113! - paragraph '0115!; figures 24-26 paragraph '0118!	1-3,5, 13,15-17
X	WO 01/21247 A (APPRIVA MEDICAL INC) 29 March 2001 (2001-03-29) page 25, line 24 - line 28; figures 24,D	1,4,7
Y	page 22, line 23 -page 24, line 27; figures 18-20	14
Y	US 5 312 438 A (JOHNSON LANNY L) 17 May 1994 (1994-05-17) the whole document	14

-/--

[X] Further documents are listed in the continuation of box C.

[X] Patent family members are listed in annex.

° Special categories of cited documents :

"A" document defining the general state of the art which is not considered to be of particular relevance
"E" earlier document but published on or after the international filing date
"L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)
"O" document referring to an oral disclosure, use, exhibition or other means
"P" document published prior to the international filing date but later than the priority date claimed
"T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention
"X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone
"Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art.
"&" document member of the same patent family

Date of the actual completion of the international search	Date of mailing of the international search report
29 April 2004	14/05/2004

Name and mailing address of the ISA	Authorized officer
European Patent Office, P.B. 5818 Patentlaan 2 NL - 2280 HV Rijswijk Tel. (+31-70) 340-2040, Tx. 31 651 epo nl, Fax: (+31-70) 340-3016	Herberhold, C

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INTERNATIONAL SEARCH REPORT

International Application No
PCT/US 03/40453

C.(Continuation) DOCUMENTS CONSIDERED TO BE RELEVANT

Category °	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	US 2001/039423 A1 (OREN RAN ET AL) 8 November 2001 (2001-11-08) figure 2	8
A	WO 01/97676 A (WILL THOMAS DAVID ;ANTAKI JAMES F (US); JOHNSON GREG A (US); CARDI) 27 December 2001 (2001-12-27) page 40, line 20 -page 42, line 15; figures 23-26	8,9
X	WO 02/17771 A (ADVANCED VASULAR TECHNOLOGIES) 7 March 2002 (2002-03-07) page 27, line 3 - line 20; figures 1C,4,5	10-12
X	WO 96/40356 A (EP TECHNOLOGIES) 19 December 1996 (1996-12-19) figure 31C	10,11

INTERNATIONAL SEARCH REPORT

International application No.
PCT/US 03/40453

Box I Observations where certain claims were found unsearchable (Continuation of item 1 of first sheet)

This International Search Report has not been established in respect of certain claims under Article 17(2)(a) for the following reasons:

1. ☐ Claims Nos.:
because they relate to subject matter not required to be searched by this Authority, namely:

2. ☐ Claims Nos.:
because they relate to parts of the International Application that do not comply with the prescribed requirements to such an extent that no meaningful International Search can be carried out, specifically:

3. ☐ Claims Nos.:
because they are dependent claims and are not drafted in accordance with the second and third sentences of Rule 6.4(a).

Box II Observations where unity of invention is lacking (Continuation of item 2 of first sheet)

This International Searching Authority found multiple inventions in this international application, as follows:

see additional sheet

1. ☐ As all required additional search fees were timely paid by the applicant, this International Search Report covers all searchable claims.

2. ☒ As all searchable claims could be searched without effort justifying an additional fee, this Authority did not invite payment of any additional fee.

3. ☐ As only some of the required additional search fees were timely paid by the applicant, this International Search Report covers only those claims for which fees were paid, specifically claims Nos.:

4. ☐ No required additional search fees were timely paid by the applicant. Consequently, this International Search Report is restricted to the invention first mentioned in the claims; it is covered by claims Nos.:

Remark on Protest

☐ The additional search fees were accompanied by the applicant's protest.

☐ No protest accompanied the payment of additional search fees.

FURTHER INFORMATION CONTINUED FROM PCT/ISA/ 210

This International Searching Authority found multiple (groups of) inventions in this international application, as follows:

1. Claims: 1-7

   A soft tissue anchor having a plurality of support members radially disposed about the central body.

2. Claims: 8,9

   A soft tissue anchor having one or more support members. each of the support members being wrapped around the central body element in a first position to permit passage of the soft tisse anchor through the soft tissue.

3. Claims: 10-12

   A soft tissue anchor comprising a distal portion comprising one or more coils.

INTERNATIONAL SEARCH REPORT

Information on patent family members

International Application No
PCT/US 03/40453

Patent document cited in search report	Publication date	Patent family member(s)	Publication date
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